

Design Control Inspection Results

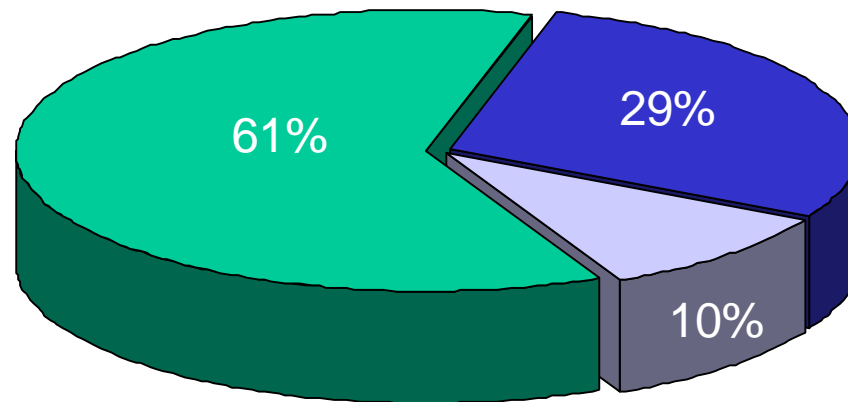
June 1, 1997

to

June 1, 1998

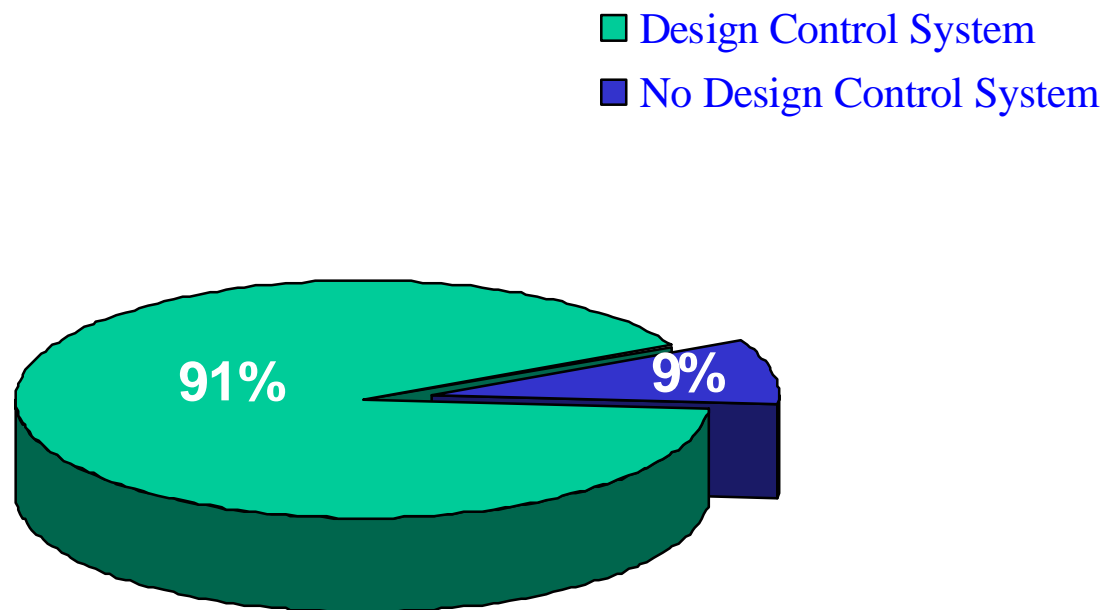
Devices Covered

- Subject to Design Controls
- Not Subject to Design Controls
- N/A



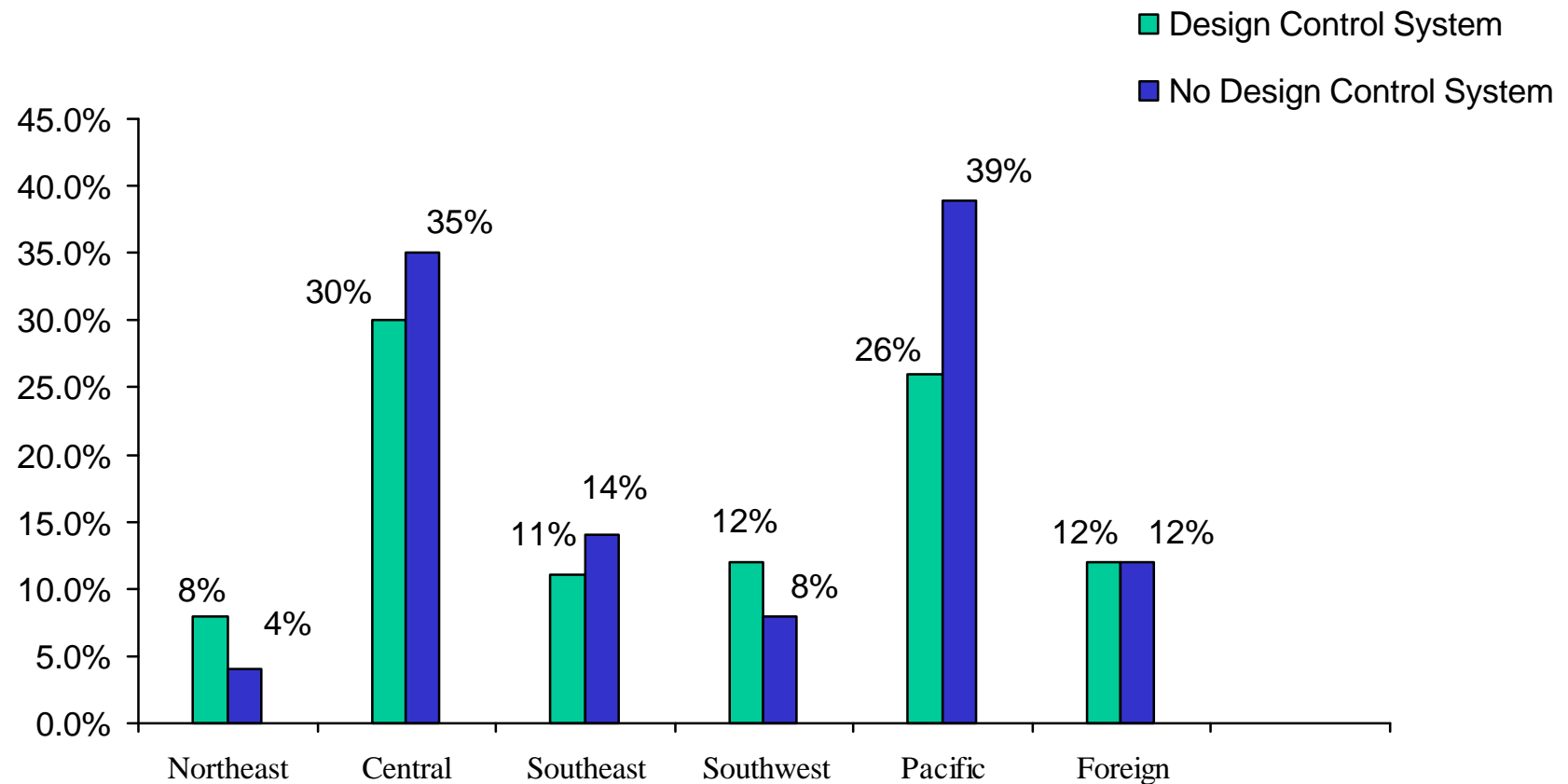
Total Firms = 582

Firms with No Design Control System



Total Firms = 582

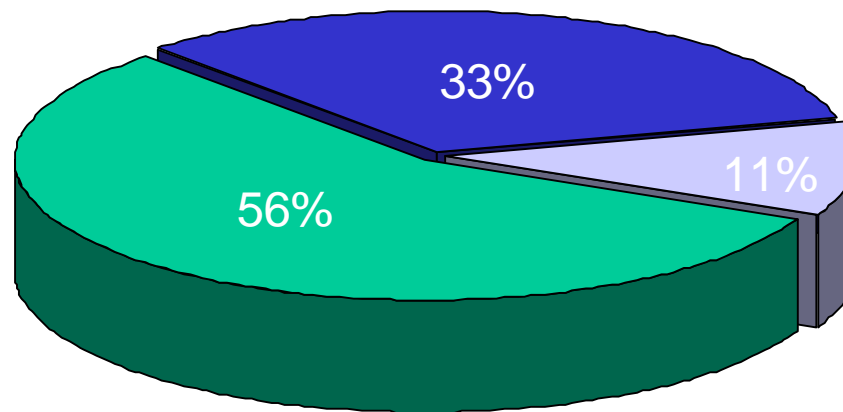
Firms with/without Design Control Systems



Total Firms = 582

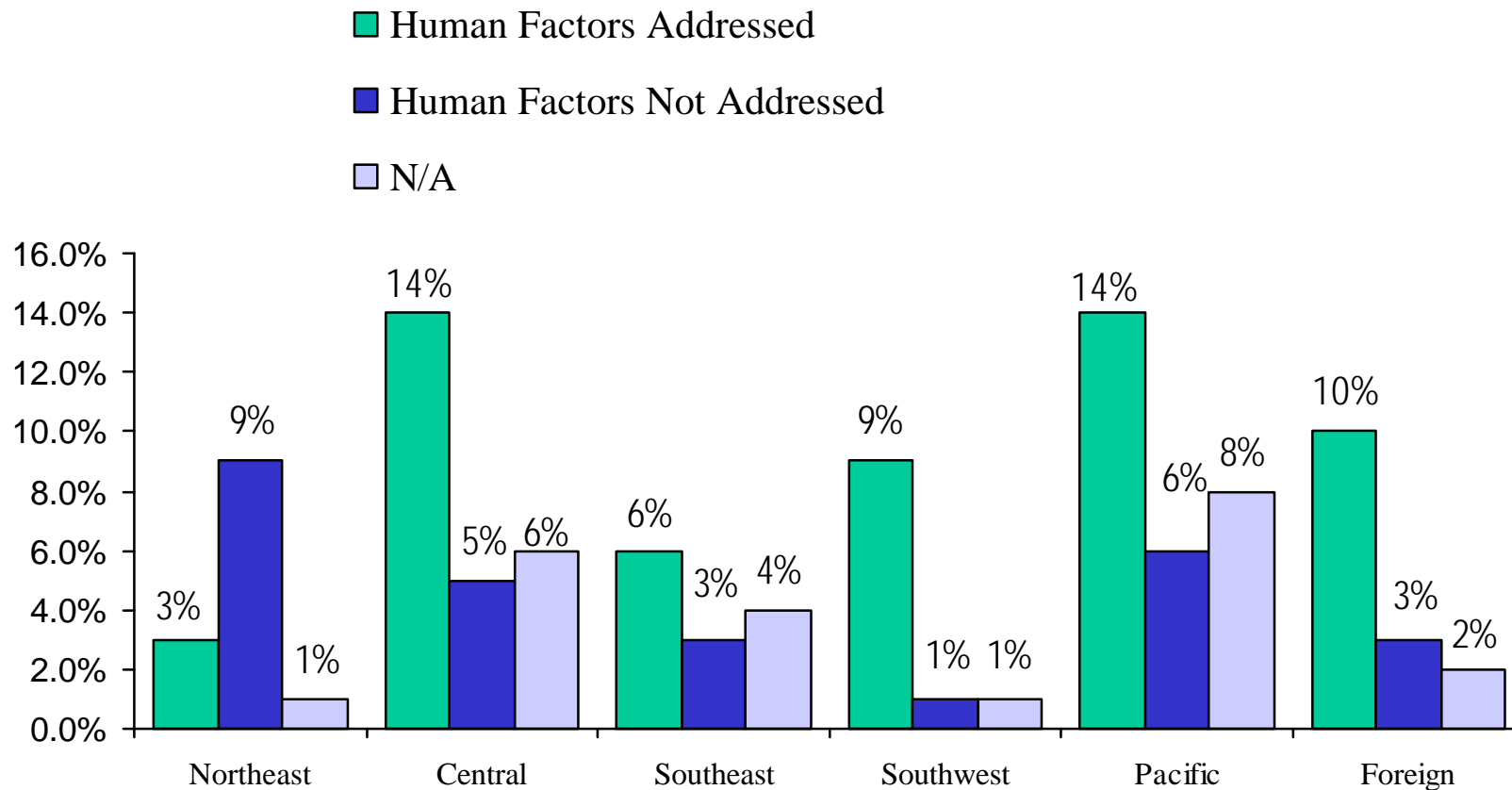
Human Factors

- Human Factors Addressed
- Human Factors Not Addressed
- Human Factors N/A



Total Firms = 582

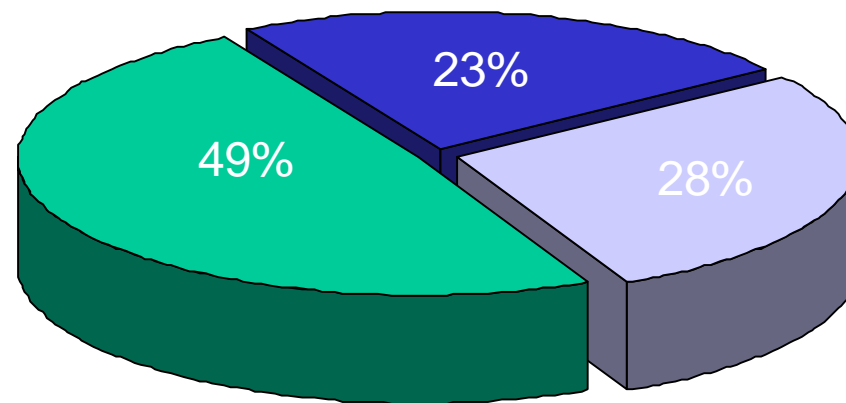
Human Factors



Total Firms = 582

Risk Analysis

- Risk Analysis Conducted
- Risk Analysis Not Conducted
- Can Not Determine



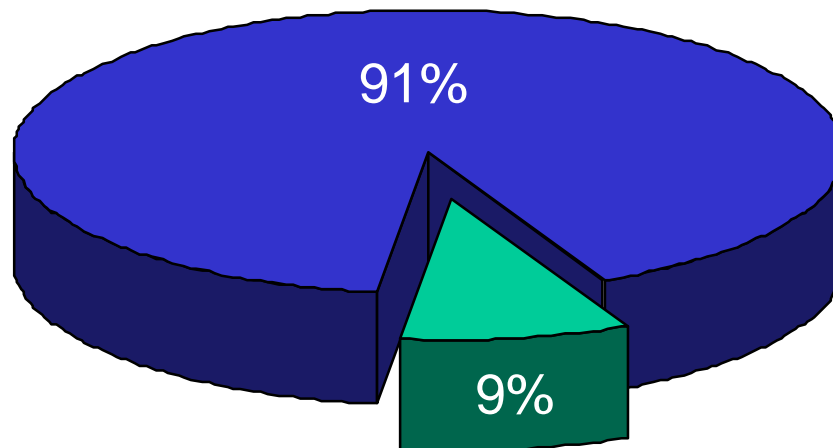
Total Firms = 582

Data Collected from Design Control Inspectional Team Evaluation of Reports

Risk Analysis Not Conducted

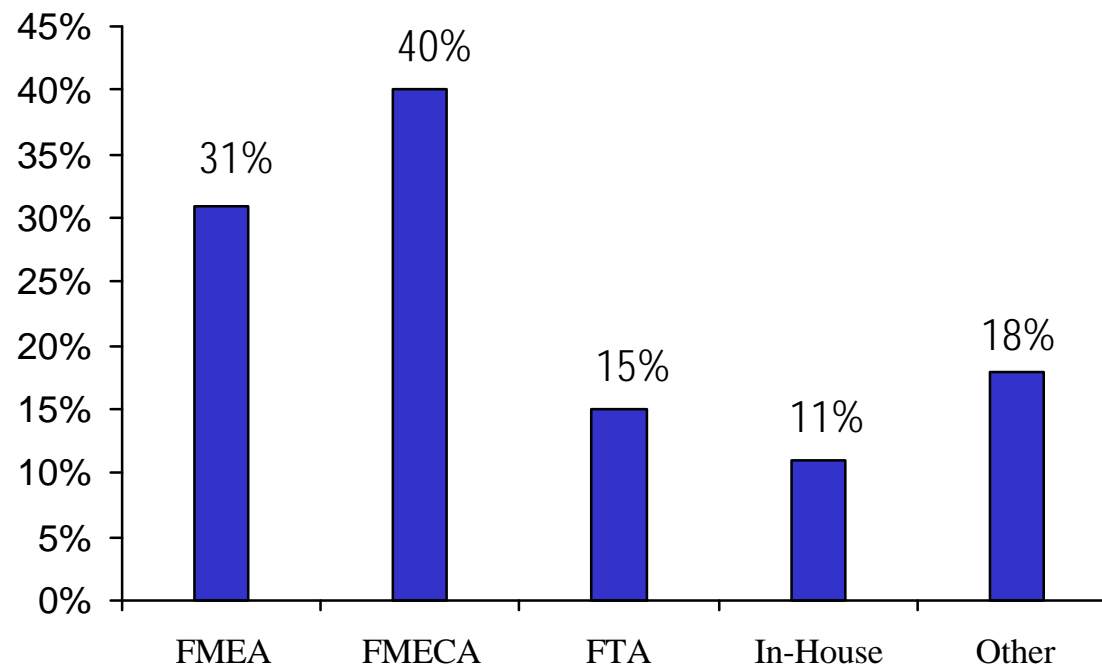
■ Justification Documented

■ Justification Not Documented



Total Firms = 134

Risk Analysis Techniques Used

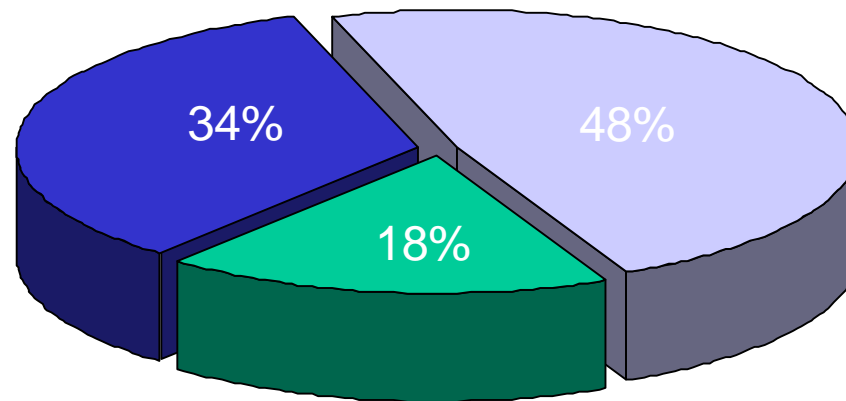


Total Records = 285

Note: Some firms used more than one technique

Electromagnetic Compatibility/ Electromagnetic Interference

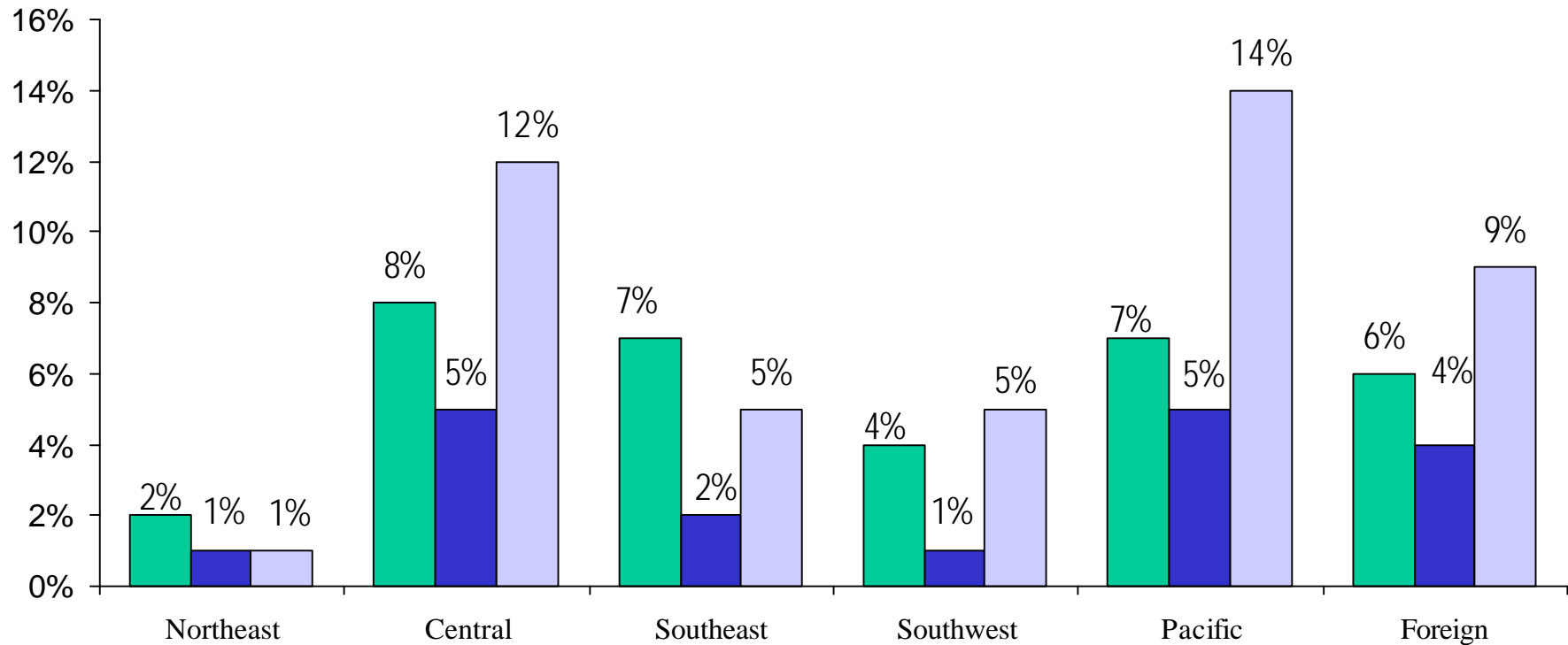
- EMC/EMI Addressed
- EMC/EMI Not Addressed
- N/A



Total Firms = 582

Electromagnetic Compatibility/ Electromagnetic Interference

■ EMC/EMI Addressed
■ EMC/EMI Addressed
■ N/A

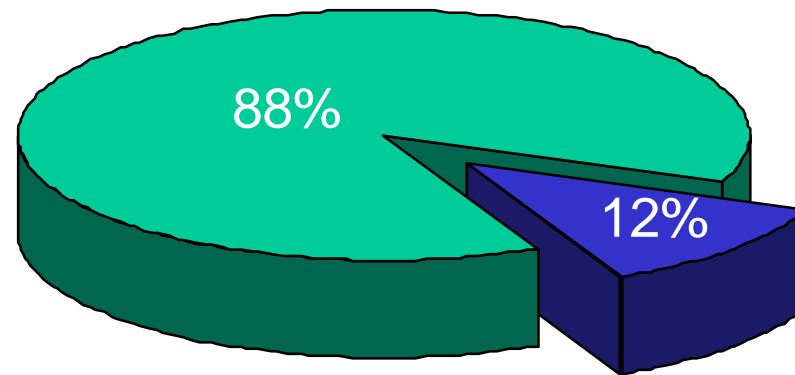


Total Firms = 582

Understanding Design Validation Vs. Process Validation

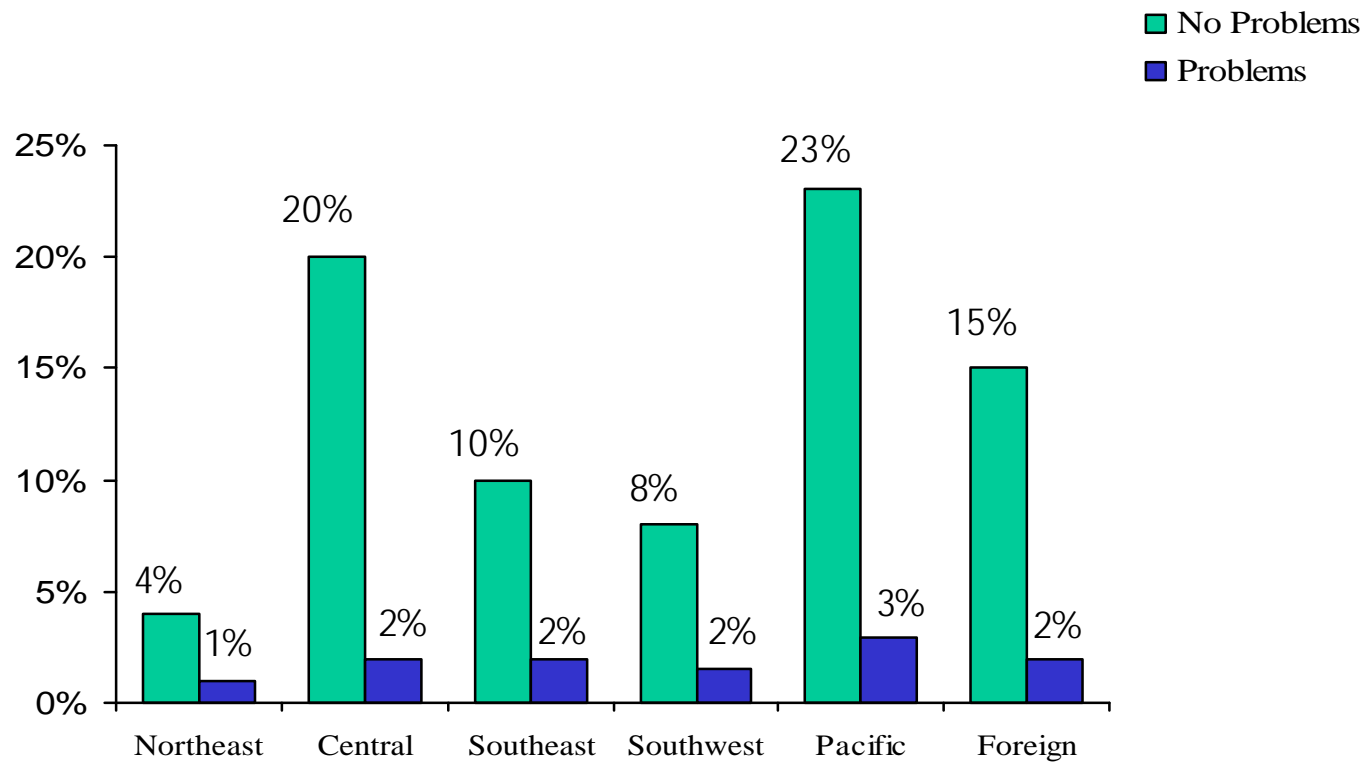
■ No
Problems

■ Problems



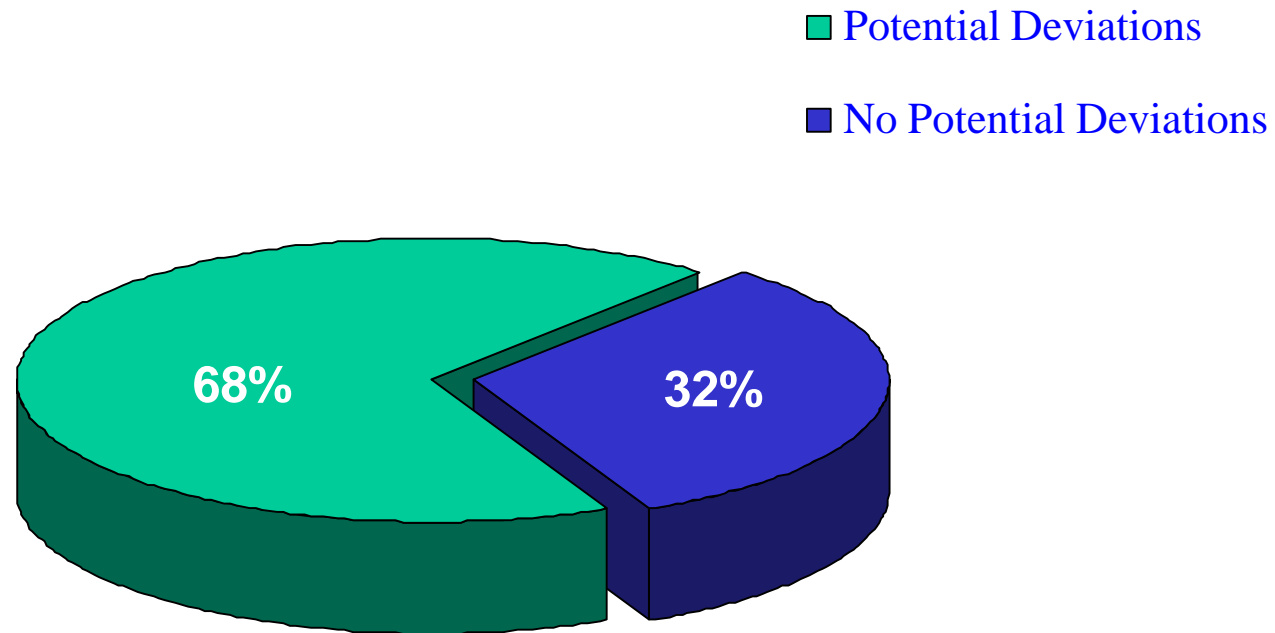
Total Firms = 582

Understanding Design Validation Vs. Process Validation



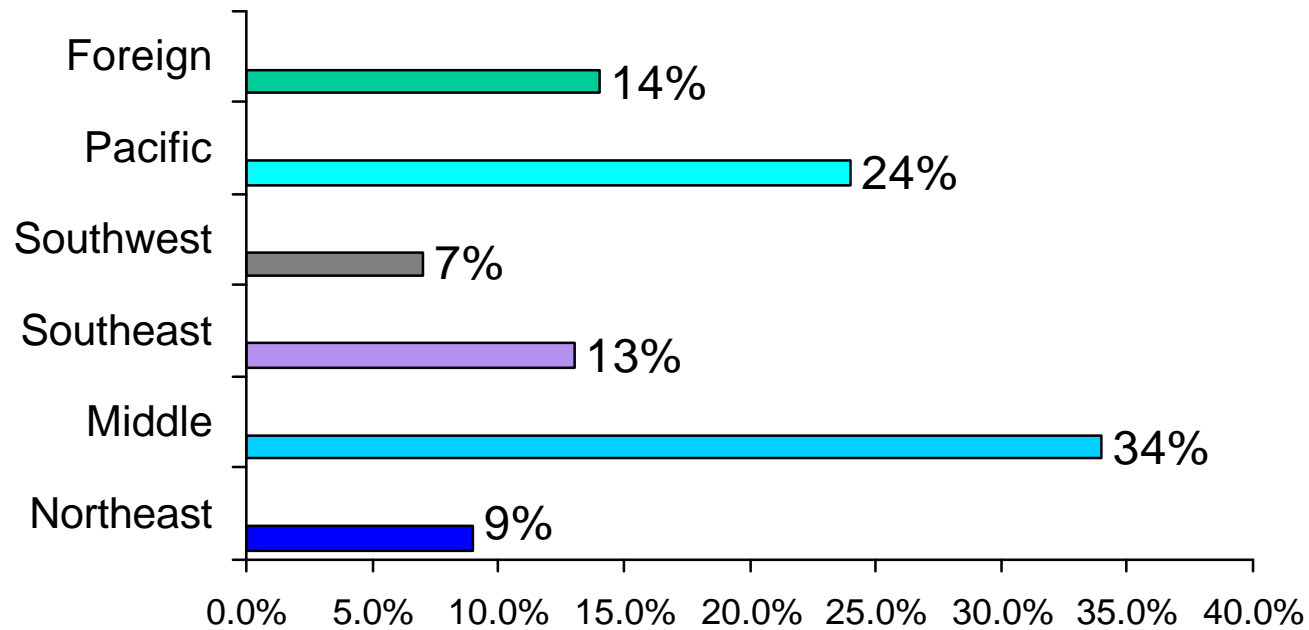
Total Firms = 582

Firms with Potential Design Control Deviations



Total Firms = 582

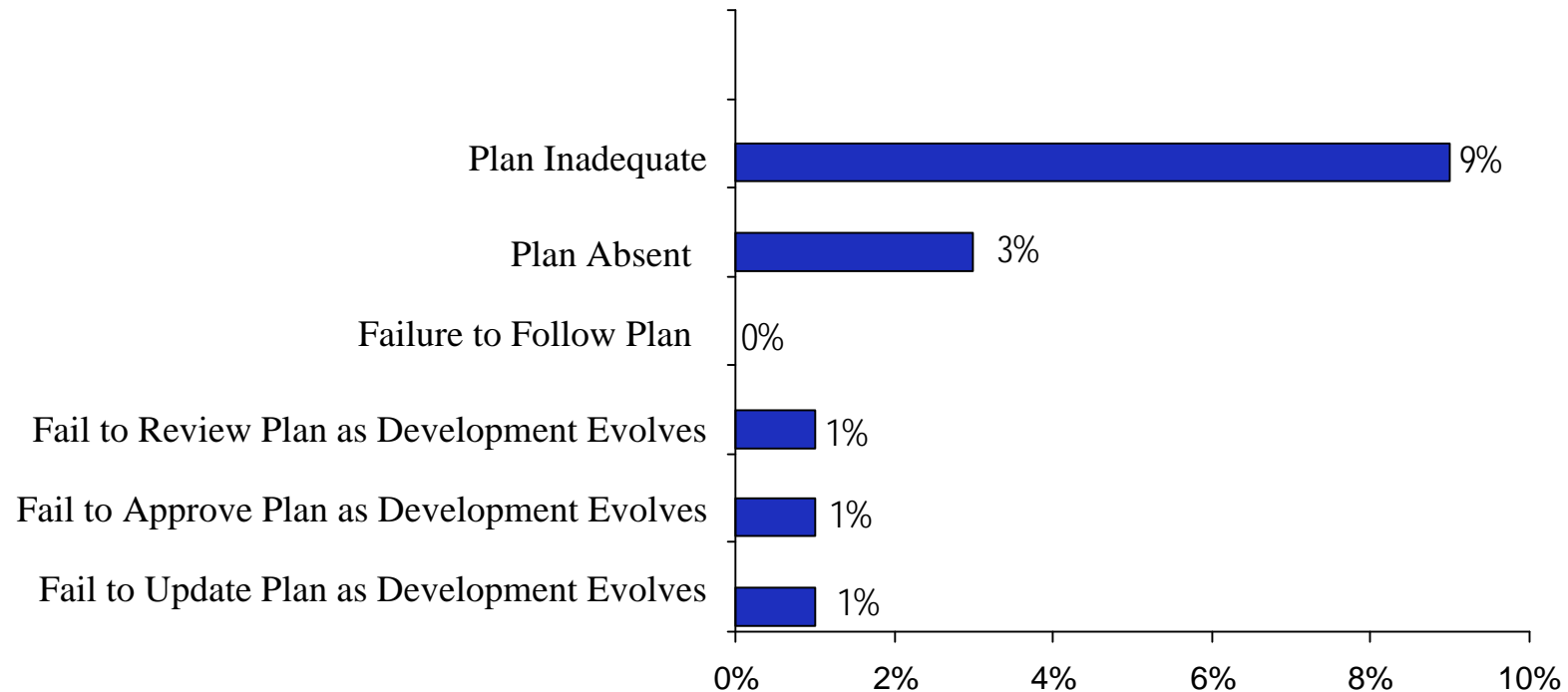
Firms with Potential Design Control Deviations



Total Firms w/ Deviations = 186

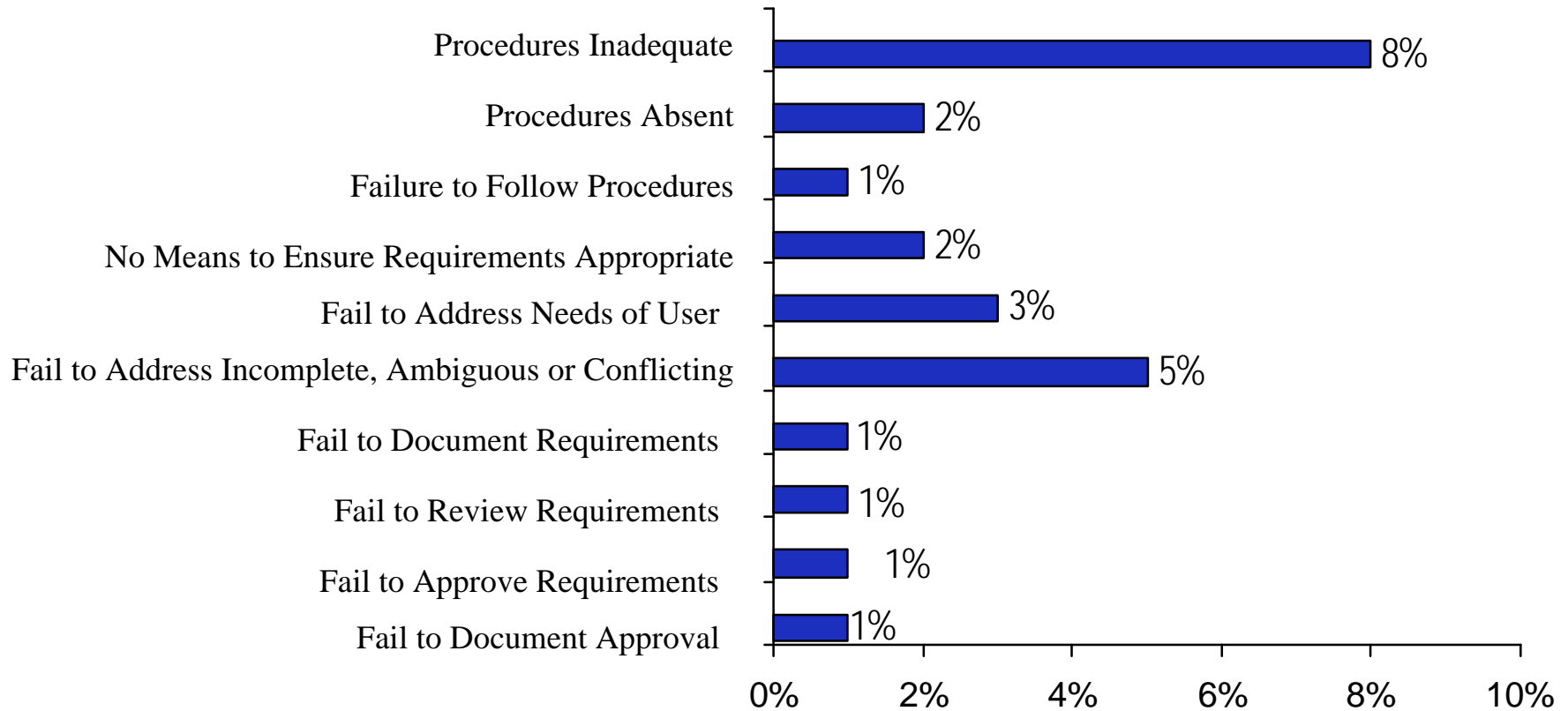
Design and Development Plan Requirements

Potential Deviations



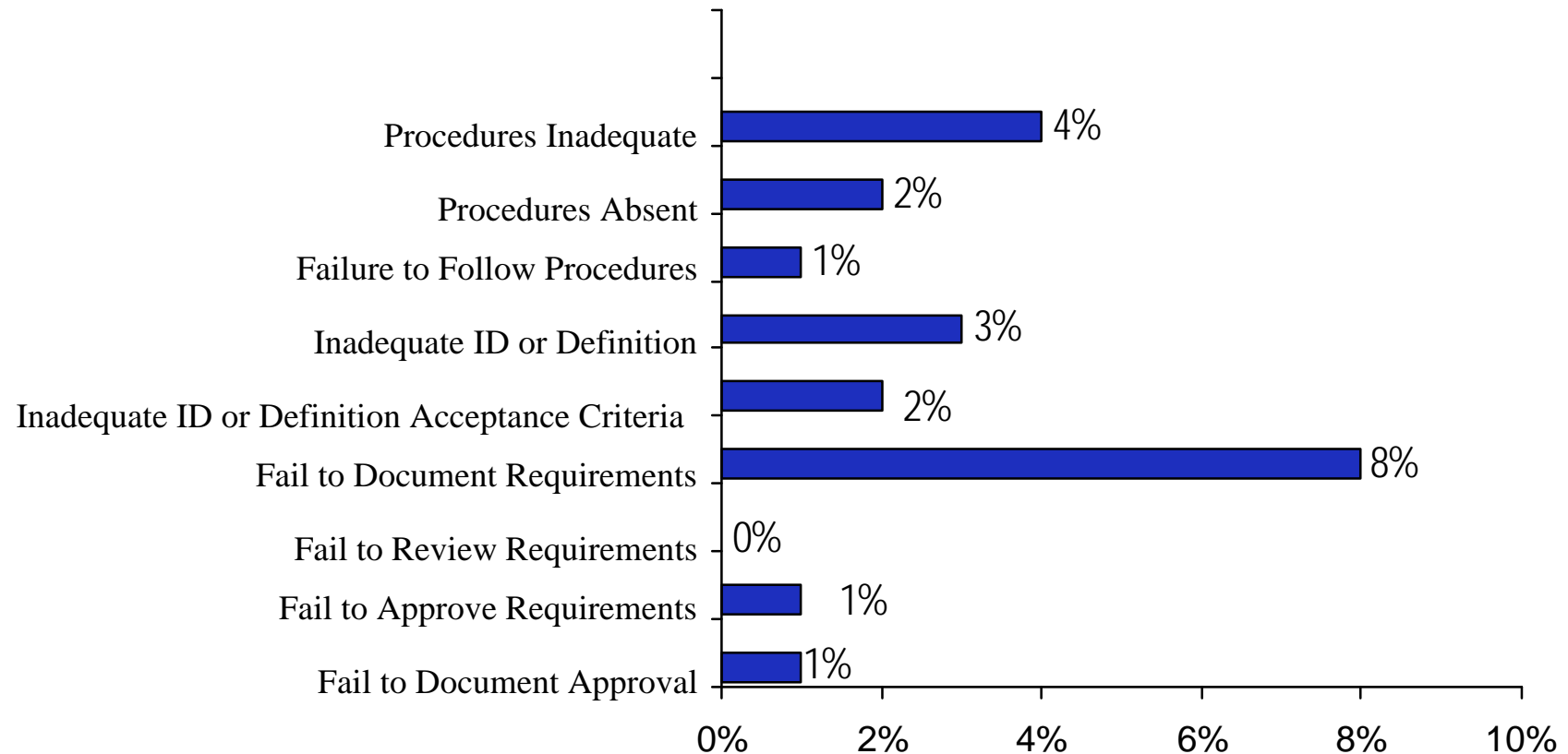
Total Firms = 582

Design Input Requirements Potential Deviations



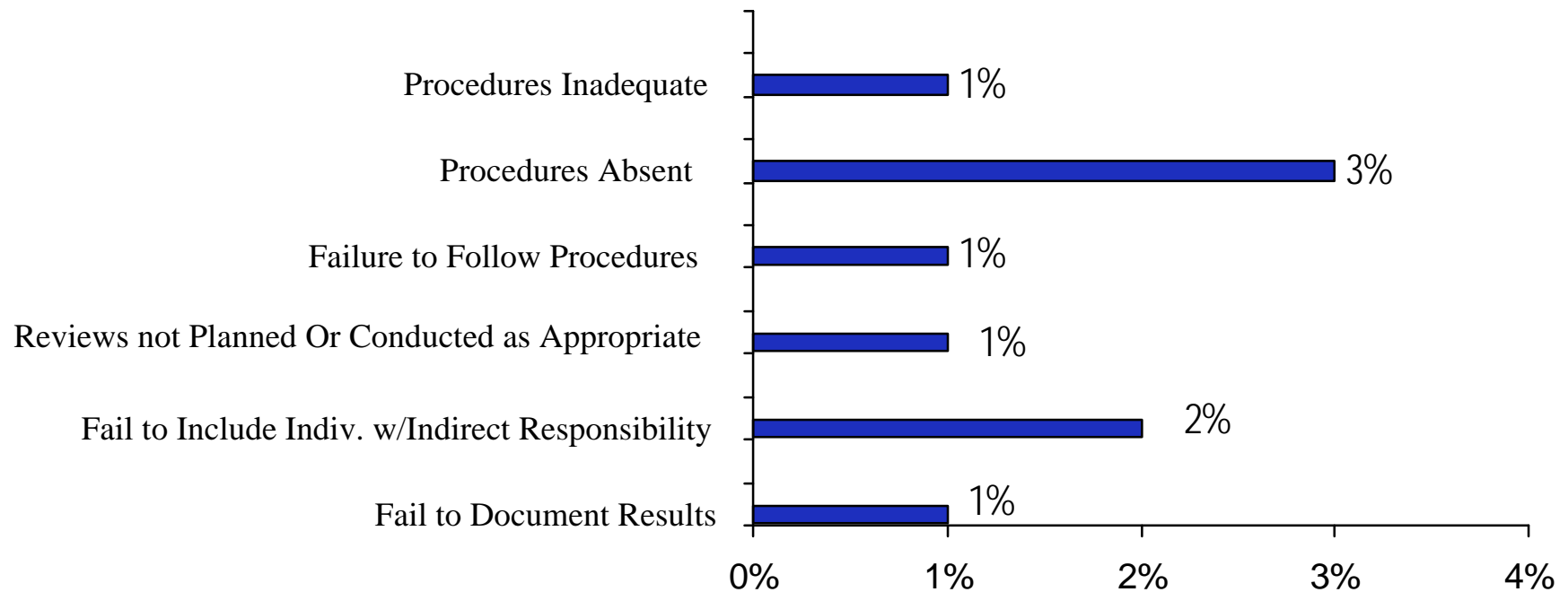
Total Firms = 582

Design Output Requirements Potential Deviations



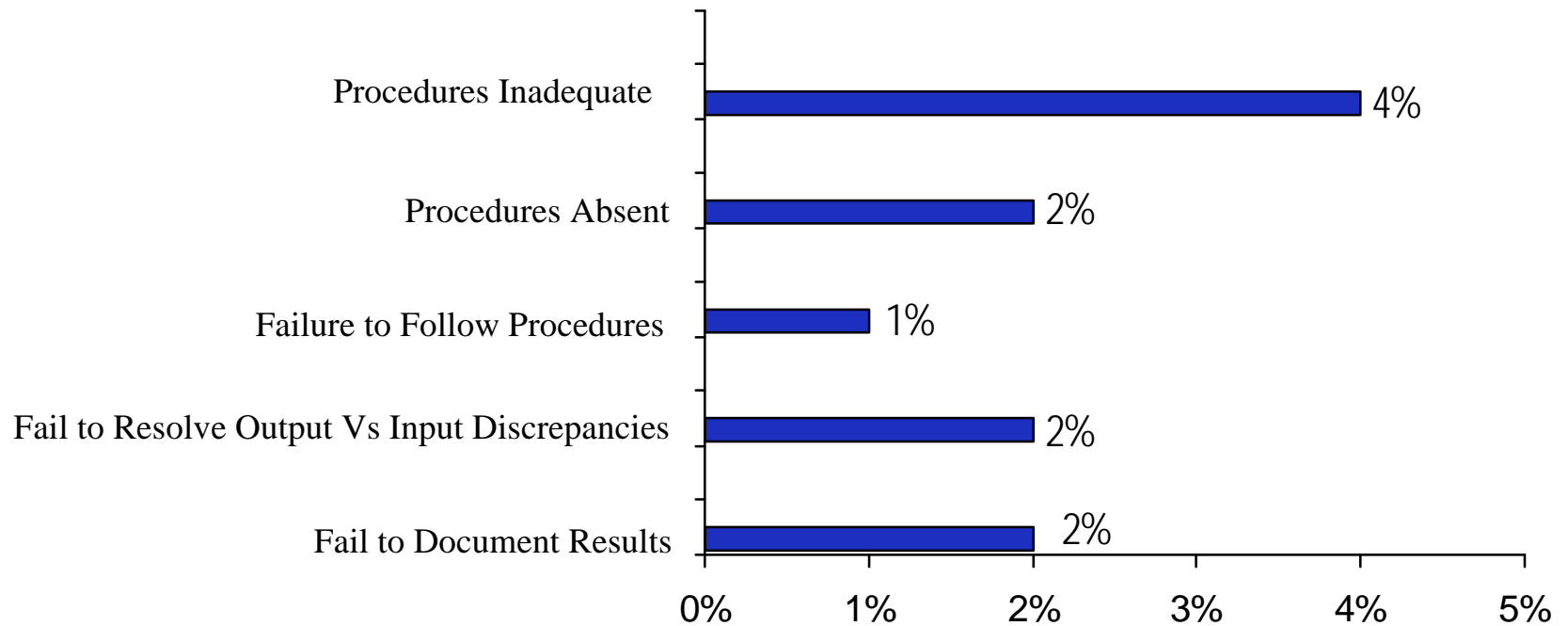
Total Firms = 582

Design Review Requirements Potential Deviations



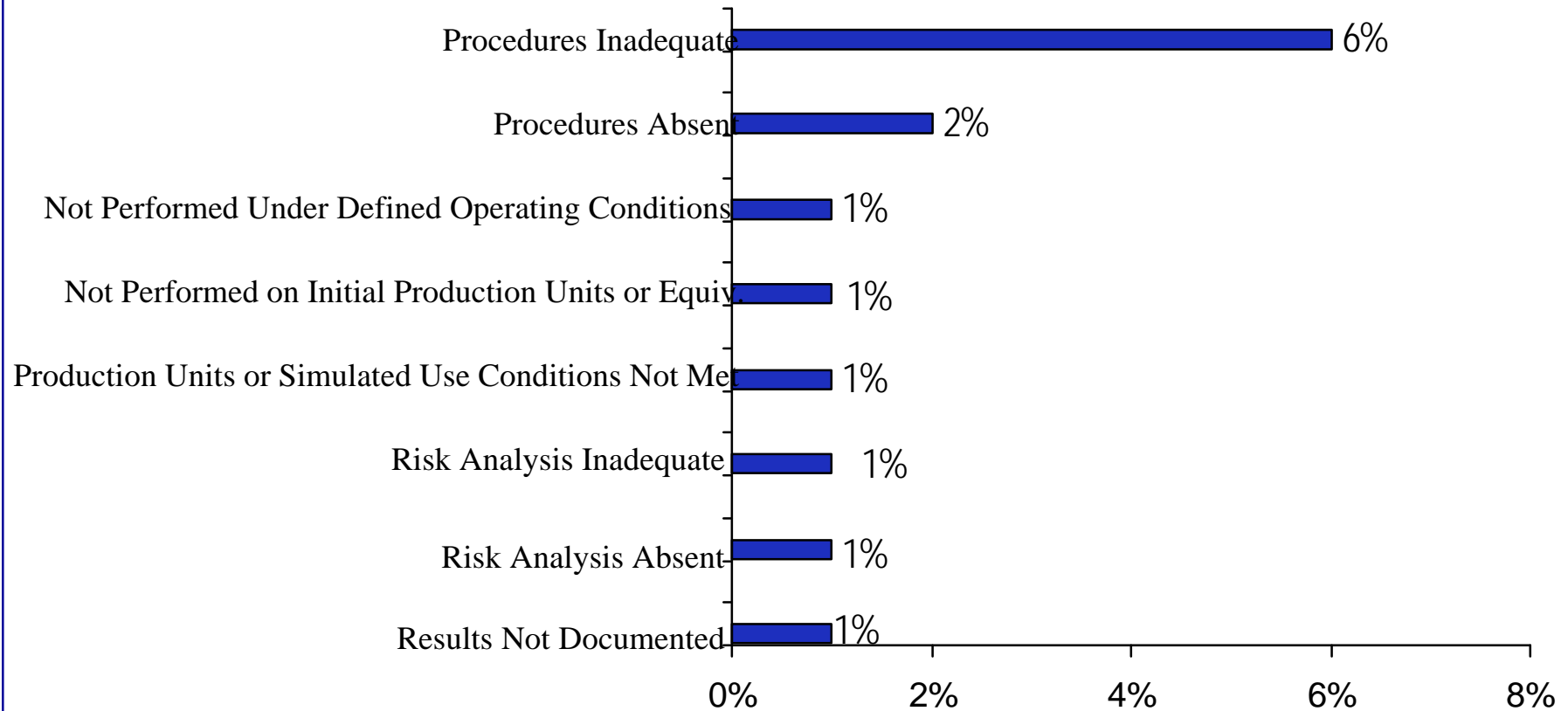
Total Firms = 582

Design Verification Requirements Potential Deviations



Total Firms = 582

Design Validation Requirements Potential Deviations

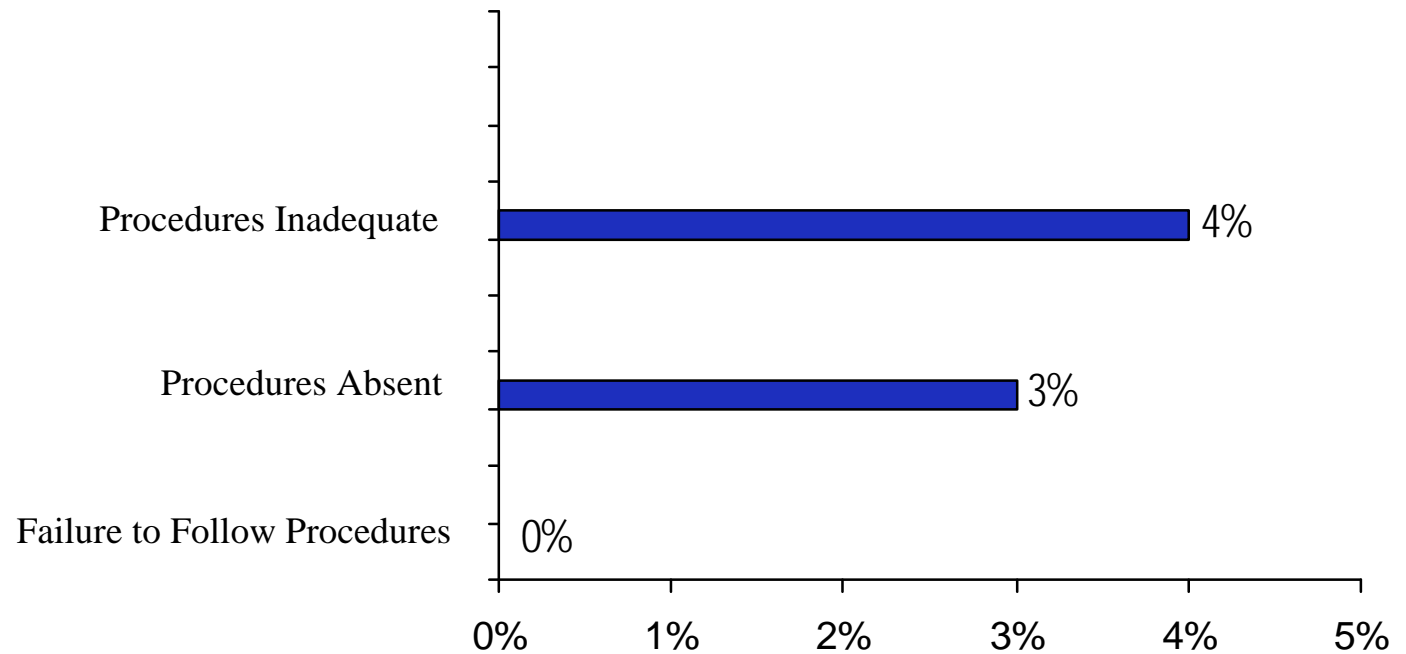


Total Firms = 582

Data Collected from Areas of Needed Improvement on Design Control Reports

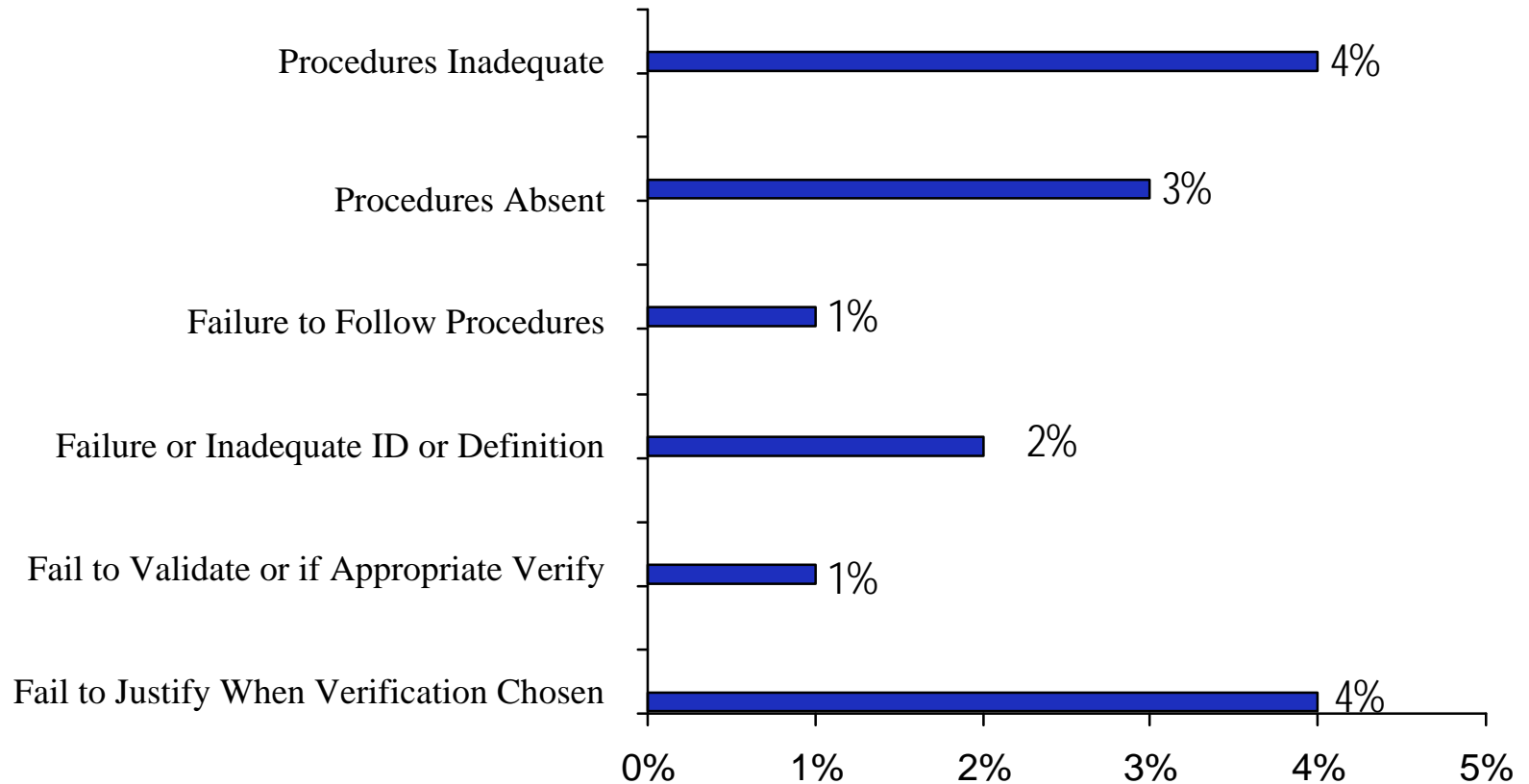
Design Transfer Requirements

Potential Deviations



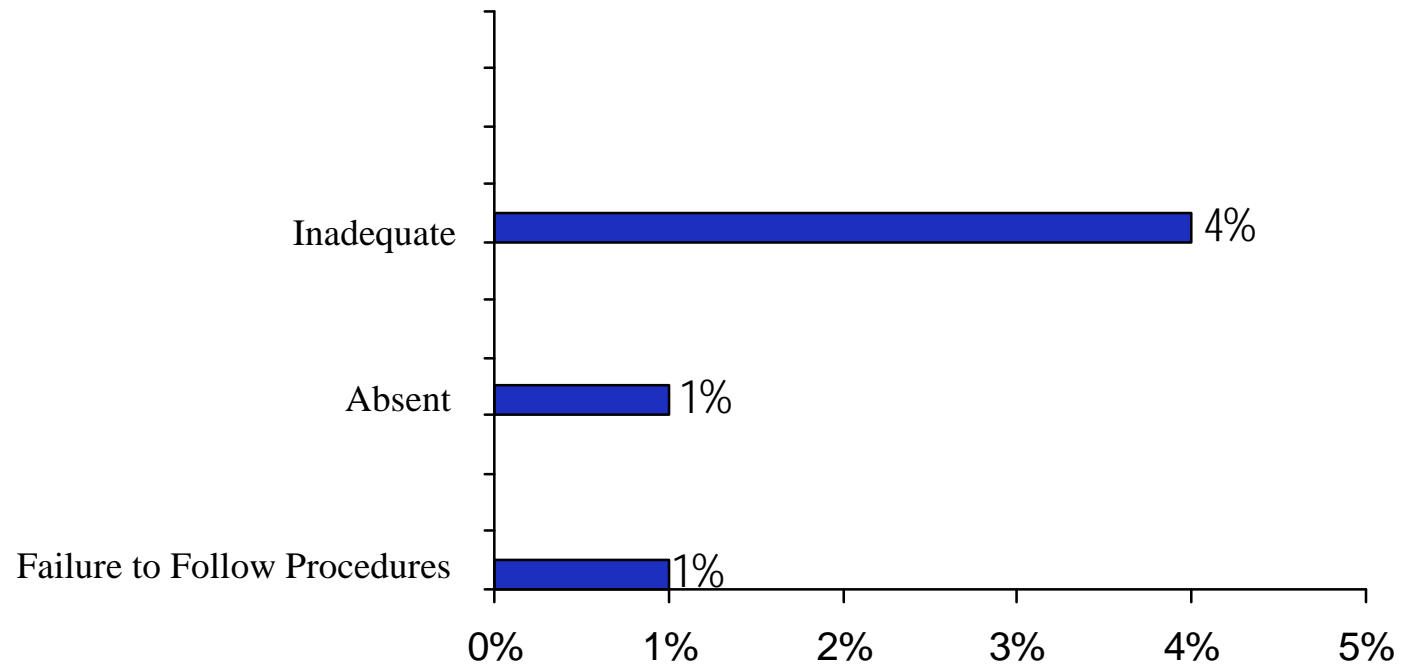
Total Firms = 582

Design Change Requirements Potential Deviations



Total Firms = 582

Design History File Requirements Potential Deviations



Total Firms = 582